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Eisai Co., Ltd.

“URECE®” (Dotinurad) Launched in China as a treatment for Gout

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that it has launched “URECE®” (brand name in China: “优乐思®”, generic name: dotinurad) in China as a treatment for Gout. URECE was approved by the National Medical Products Administration in China as a treatment for gout patients with hyperuricemia in December 2024.

URECE is a new therapeutic medicine for gout and hyperuricemia discovered by FUJI YAKUHIN. It suppresses uric acid reabsorption and lowers blood uric acid levels by selectively inhibiting the urate transporter (URAT1) related to reabsorption of uric acid in the kidney.

Eisai concluded a license agreement with FUJI YAKUHIN for China and five ASEAN member states: Indonesia, Malaysia, Myanmar, the Philippines, and Thailand, granting exclusive development and distribution rights in these countries. This approval in China is based on the results of a multicenter, active-controlled, double-blind, parallel-group, randomized, Phase 3 study of 451 gout patients conducted in China by Eisai.[1] The results of this study showed that the proportion of subjects with serum uric acid levels of 6.0 mg/dL or less at 24 weeks, which was the primary endpoint, was 73.6% [95% confidence interval (CI): 67.8, 79.5] in the dotinurad group and 38.1% [95% CI: 31.6, 44.5] in the comparator febuxostat group, confirming the statistical superiority of dotinurad 4 mg over febuxostat 40 mg (difference of proportion 35.87% [95% CI: 27.36, 44.37, $p<0.001$]) (see “Notes to Editors” section “3. About the Phase 3 Clinical Trial”). Eisai has obtained approval for dotinurad in China, Thailand and the Philippines.

Gout can develop at any age, is more common in men than women, and during an acute attack, can cause severe joint pain, swelling, redness, and inflammation. The pain gradually improves over a few days, but can sometimes last for weeks. If left untreated, the joint tissue may become damaged and deformed, leading to restrictions in daily activities and a decrease in quality of life.[2]

The prevalence of gout is increasing, and it is estimated that there are currently about 23 million patients with gout in China.[3] It is expected that the number of patients will further increase in the near future due to changes in lifestyle and dietary preferences in accordance with socioeconomic development.
Eisai is committed to providing URECE to more patients with gout in China as a new treatment option, and will contribute to improving the quality of life (QOL) of patients.

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<Notes to editors>

1. “优乐思®” Product Outline

Chinese Trade name: “优乐思” (URECE)
Chinese generic name: 多替诺雷片 (Dotinurad Tablets)
Indication for use: It is indicated for gout patients with hyperuricemia.
Dosage and administration: For oral use, the usual adult initial dosage is 1 mg of dotinurad once daily. The dose level should then be gradually increased as needed by checking blood uric acid levels. The usual maintenance dosage is 2 mg once daily and may be adjusted according to the patient’s condition, but up to 4 mg once daily.

2. About “URECE®” (Dotinurad)

URECE is a therapeutic medicine for gout and hyperuricemia discovered by FUJI YAKUHIN. URECE selectively inhibits URAT1, one of the uric acid transporters, thus preventing reabsorption of uric acid by the kidneys and promoting uric acid excretion in the urine. In addition, URECE has a small effect on other transporters affecting uric acid secretion, so it reduces serum uric acid levels at lower doses. URECE is expected to have a low risk of side effects and drug interactions. In Japan, FUJI YAKUHIN obtained manufacturing and marketing approval for URECE in January 2020 and launched it in May 2020.
Eisai concluded a license agreement with FUJI YAKUHIN for China and five ASEAN member states: Indonesia, Malaysia, Myanmar, the Philippines, and Thailand, granting exclusive development and distribution rights in these countries. URECE was approved in Thailand for gout and hyperuricemia in Thailand in September, 2024 and in the Philippines in February, 2025.

3. About the Phase 3 Clinical Trial (Study FYU-981-J086-301)[1]

This was a multicenter, active-controlled, double-blind, parallel-group, randomized, Phase 3 study conducted to confirm the superiority of dotinurad 4 mg over febuxostat 40 mg as the primary endpoint, assess safety, and confirm the non-inferiority of dotinurad 2 mg to febuxostat 40 mg as the secondary endpoint in Chinese patients with gout.
Patients with gout and serum uric acid (SUA) levels exceeding 7.0 mg/dL were randomly assigned to either the dotinurad group or the febuxostat group in a 1:1 ratio, investigational product treatment for 24 weeks (the dotinurad group received 1 mg/day for 4 weeks, 2 mg/day for 8 weeks, and 4 mg/day for 12 weeks, while the febuxostat group received 20 mg/day for 4 weeks and 40 mg/day for 20 weeks). The primary endpoint was the proportion of patients with SUA ≤6.0 mg/dL at 24 weeks, and the secondary endpoint was the proportion of patients with SUA ≤6.0 mg/dL at 12 weeks.
Of the total 451 patients, 225 were assigned to the dotinurad group and 226 to the febuxostat group. Of these, 441 patients (220 in the dotinurad group and 221 in the febuxostat group) were included in the Full Analysis Set (FAS).
For the primary endpoint, the proportion of patients with SUA ≤6.0 mg/dL at 24 weeks was 73.6% [95% confidence interval (CI): 67.8, 79.5] in the dotinurad group and 38.1% [95% CI: 31.6, 44.5] in the febuxostat group, confirming the statistical superiority of dotinurad 4 mg over febuxostat 40 mg (difference of proportion 35.87% [95% CI: 27.36, 44.37, $p<0.001$]).
For the secondary endpoint, the proportion of patients with SUA ≤6.0 mg/dL at 12 weeks was 55.5% in the dotinurad group and 50.5% in the febuxostat group, confirming the statistical non-inferiority of dotinurad 2 mg to febuxostat 40 mg (difference of proportion 5.24% [95% CI: -3.69, 14.17]).

The most common adverse events were gouty arthritis, COVID-19, and liver function abnormality in the dotinurad group, and gouty arthritis, COVID-19, and increased alanine aminotransferase (ALT) in the febuxostat group. No new safety concerns with dotinurad were observed.

References

1. Sun J, Wang Y, Zhang X, *et al*. POS0255 A RANDOMIZED, MULTICENTER, DOUBLE-BLIND, PHASE 3 STUDY COMPARING EFFICACY OF DOTINURAD AND FEBUXOSTAT FOR THE TREATMENT OF GOUT IN CHINESE SUBJECTS. *Annals of the Rheumatic Diseases* 2024;83:407-408.
2. Huang, J., Ma, Z.F., Tian, Y. *et al*. Epidemiology and Prevalence of Gout in Mainland China: an Updated Systematic Review and Meta-Analysis. *SN Compr. Clin. Med.* 2, 1593–1606 (2020).
3. Estimated data calculated from reference 2 and United Nations World Population Estimates - World Population Prospects, URL：https://population.un.org/wpp/